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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,807	07/16/2001	Helen Rachel Crooke	GJE-65	2112

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,807	Applicant(s) CROOKE ET AL.	
	Examiner Ja-Na A Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4 and 13, drawn to an isolated peptide and transformed host.

Group II, claim(s) 3 and 12, drawn to an isolated polynucleotide.

Group III, claim(s) 5 and 14, drawn to a vaccine comprising a peptide or the means for its expression.

Group IV, claim(s) 6-8 and 15-17, drawn to a vaccine comprising a microorganism having a virulence gene mutation.

Group V, claim(s) 9, 18-19, drawn to a method for screening potential drugs or for the detection of virulence.

Group VI, claim(s) 10,11, 20-21, drawn to a method for treatment or prevention of a condition associated with infection by a gram-negative bacterium comprising administering a vaccine.

Group VII, claim(s) 22, drawn to a method for treatment or prevention of a condition associated with infection by a gram-negative bacterium comprising administering a nucleotide to a person or animal in need thereof.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: SEQ ID NO: 2, 5, 7, 9, 11, 12, 13, 14, 16, 18, 19, 21, 23, 24, 25, 26, 28, 29, 31, 32 and 35-48. The sequences do not form a single general inventive

concept because: The methods rely upon the products of the peptides selected from SEQ ID NO: 2, 5, 7, 9, 11, 12, 13, 14, 16, 18, 19, 21, 23, 24, 25, 26, 28, 29, 31, 32 and 35-48 which are distinct physically, structurally, and functionally as determined by ~~there~~ different SEQ ID Numbers, are patentably distinct, each group from the other. ~~And~~ One sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences which do not share a substantial structural feature disclosed as being essential to the utility of the invention.

The species are as follows: *tatA, tatB, tatC, tatE, mdoG, creC, recG, yggN, eck1, iroD, iroC, iroE, mtd2* and *ms1* to *ms16*.

The operons do not form a single general inventive concept because: The operons do not form a single general inventive concept because: The methods rely upon the products of the operons selected from *tatA, tatB, tatC, tatE, mdoG, creC, recG, yggN, eck1, iroD, iroC, iroE, mtd2* and *ms1* to *ms16* which are distinct physically, structurally, and functionally as determined by ~~there~~ different operons names and associated functions, and are patentably distinct, each group from the other. One operon is not required to practice the other. Each group comprises separate and distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: The following claim(s) are generic: 1-22.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different product inventions are: Group I is drawn to an isolated peptide and transformed host; Group II, is drawn to an isolated polynucleotide; Group III is drawn to a vaccine comprising a peptide or the means for its expression; Group IV is drawn to a vaccine comprising a microorganism having a virulence gene mutation. Each product has a different special technical feature, i.e., the vaccine has the ability to induce a productive

immune response unlike any other group however the vaccine comprises different components when comparing groups III and IV. The peptide and polynucleotide of groups II and I are structurally different and have different functions which allow for different technical features. Accordingly, the groups lack the same technical feature.

Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different product inventions are: Group V is drawn to a method for screening potential drugs or for the detection of virulence; Group VI is drawn to a method for treatment or prevention of a condition associated with infection by a gram-negative bacterium comprising administering a vaccine; Group VII is drawn to a method for treatment or prevention of a condition associated with infection by a gram-negative bacterium comprising administering a nucleotide to a person or animal in need thereof.

Each method comprises a variety of different reagents and components capable of performing specific functions, whereas the other methods do not requires the specific use of said components. The methods have different special technical features when compared to the other method claims, i.e., the recited components comprising a vaccine comprised of a peptide as compared to a nucleotide. The method's special technical features are comprised within the steps of the method for screening potential drugs or the detection of virulence. Accordingly, the groups lack the same technical feature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines JH
October 7, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600